UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,579	10/12/2005	Marco Maria Gentile	3765-0114PUS1	1844

2292 7590 08/25/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
PUTTLITZ, KARL J	

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/531,579	GENTILE ET AL.	
	Examiner	Art Unit	
	Karl J. Puttlitz	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The objection to the specification is withdrawn in view of the substitute abstract and the amendments adding a brief description of the drawings.

The rejection under section 112, second paragraph is maintained, in part, and repeated below. Applicant's remarks in connection with this ground of rejection are also addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the pharmaceutical compositions are free of "supporting substances". It is unclear if Applicant intends to cover other anti-inflammatory agents, excipients, diluents, surfactants etc. Specifically, claim 3 recites buffers (i.e., sodium bicarbonate), which can be considered a supporting substance.

Applicant argues that another U.S. patent defines "supporting substance", and, by that definition, the term is clear. However, notwithstanding a definition in other

disclosures, the instant specification does not contain an appropriate definition, and therefore, in view of the specification, the term is still unclear.

By the instant amendments, proper antecedent basis is given in claim 2 for L-lysine salt of ketoprofen.

The prior art rejections are maintained and repeated below. Applicant remarks in connection with these grounds of rejection are also addressed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,342,530 to Darko (Darko).

Claim1 recites a pharmaceutical composition suitable for parenteral administration having anti-inflammatory and analgesic property, characterized in that it contains an alkylammonium salt of a 2-arylpropionic acid selected from ketoprofen, ibuprofen, naproxen or tiaprofenic acid, in racemic or in enantiomeric form, in an aqueous solution at a pH in the range between 8 and 9, said solution being free of preservatives, co-solvents and supporting substances.

With regard to the above embodiments, Darko teaches, in Example 4, a formulation of ibuprofen lysinate substantially free of any excipient, organic solvent, buffer, acid, base, or salt. The example makes reference to the subsequent tables, in which samples having a pH of 6.5-8.5 are recorded, see Table 1.

The forgoing anticipates claim 1 within the meaning of section 102.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darko in view of U.S. Patent No. 5,895,789 to Gentile et al. (Gentile).

Claim 2 covers those embodiments wherein the alkylammonium salt of a 2-arylpropionic acid is an L-lysine salt of ketoprofen.

Claim 3 covers those embodiments wherein the L-lysine salt of ketoprofen (claim 2) contains sodium bicarbonate and sodium hydroxide.

Darko fails to explicitly teach the embodiments set forth in claims 2 and 3. It is for this proposition that the examiner joins Gentile. Specifically, Gentile teaches that other alkylammonium salts of 2-arylpropionic acids, such as ketoprofen lysinate, are prepared for injection without preservatives. see column 3, lines 8-32. In this

connection, Darko even acknowledges that other alkylammonium salts of 2-arylpropionic acid are known to be prepared in the same manner, see description bridging columns 1 and 2 of Darko. Moreover, Darko teaches that sodium hydroxide is added to such preparations, see example 4. Therefore, those of ordinary skill would have been motivated to modify Darko to include other alkylammonium salts of 2-arylpropionic acids, such as an L-lysine salt of ketoprofen, since Gentile teaches that these agents are also beneficial in parenteral preparations. Therefore, claims 2 and 3 are prima facie obvious in view of Darko and Gentile since these references teach the elements of the rejected claims with a reasonable expectation of success.

Response to Arguments

Applicant argues that the examiner misinterprets the Darko reference. Specifically, applicant argues that consideration of the reference as a whole shows that Table 1 merely provides data recorded as the solution for injection is being prepared. See, col. 4, line .66 to col. 5, line 2. This portion of the text makes clear that the solution is mixed, the pH is measured and then, the PH is again adjusted outside the range required by the instant claims. Applicant then concludes that Darko et al. have no appreciation that an ibuprofen solution for injection should be prepared at pH 8 to 9, and it is not their intent to produce such a solution.

However, the claims are drawn to a composition with a particular pH from 8 to 9. As even applicant admits, Darko teaches the composition in that pH range. Therefore, the reference still anticipates the claimed composition since it teaches every aspect of

the claimed composition. With regard to the recitation that the composition is for parenteral administration, this is merely an intended use of the claimed composition, and not given weight.

Applicants also argue that gentile fails to remedy the deficiencies of Darko, since Gentile fails to teach the required pH range. However, based on the above, Darko anticipates the claimed composition. As stated in the rejection, Gentile teaches other alkylammonium salts of 2-arylpropionic acids, such as an L-lysine salt of ketoprofen, and those of ordinary skill would have been motivated to modify the disclosure of Darko to these agents since they are recognized as beneficial in parenteral preparations, based on the combination of Darko and Gentile. The remarks do not address this prima facie case.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at telephone number (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karl J. Puttlitz
Assistant Examiner

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
Thurman K. Page
Supervisory Patent Examiner
Art Unit 1621
Technology Center 1600

571-272-0602